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(71) Applicant *(for all designated States except US)*: **BY-PASS, INC.** [US/US]; 40 Ramland Road, Orangeburg, NY 10962 (US).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **LOSHAKOVE, Amir** [IL/IL]; P.O. Box 378, 60944 Moshav-Bazra (IL). **KILEMNIK, Ido** [IL/IL]; 35 Nordau Street, 46585 Herzelia (IL).

(74) Agents: **FENSTER, Paul** et al.; Fenster & Company, Intellectual Property 2002 LTD., P. O. Box 10256, 49002 Petach Tikva (IL).

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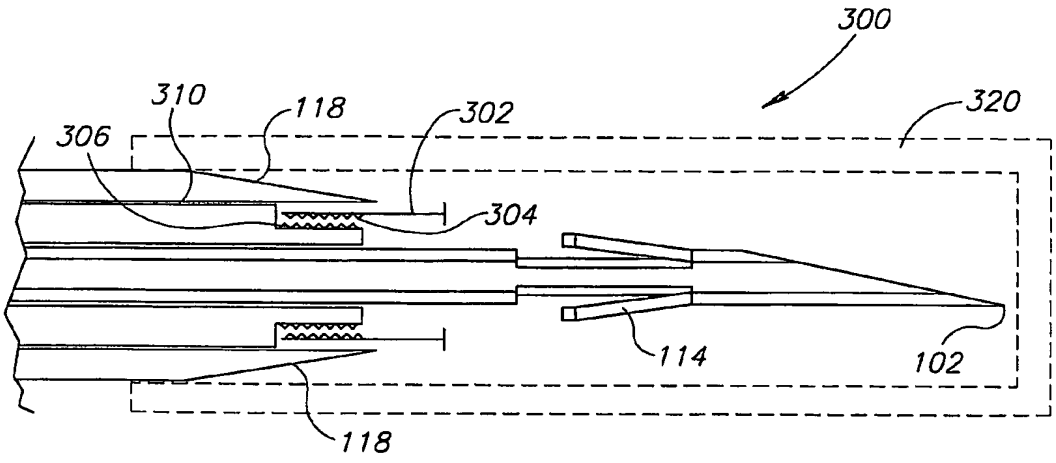

(57) Abstract: A hole former for forming an opening in a blood vessel. The hole former includes a penetration tip (102) adapted to be inserted through a wall of a blood vessel, a trigger (120) which is actuated when the penetration tip is inserted up to a predetermined distance into the blood vessel, and a power source adapted to initiate a cutting process of a blood vessel, responsive to actuation of the trigger (120).

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FORMING APERTURES IN HOLLOW ORGANS

RELATED APPLICATIONS

The present application claims priority from and is a continuation-in-part of PCT application PCT/IL03/00771 filed on September 25, 2003 and PCT/IL03/00959, filed on November 13, 2003. This application also claims priority as well as the benefit under 119(e) of USSN 60/492,998, filed on August 7, 2003 and 60/505,946 filed on September 25, 2003. The disclosures of all of these applications are incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates to medical tools for forming openings in hollow organs, such as blood vessels.

BACKGROUND

Holes are formed in blood vessels for various reasons, principal among which are (a) for insertion of a tube and (b) forming an anastomosis connection between a graft and the blood vessel.

One type of hole former for blood vessels includes a sharp edge that is inserted to the blood vessel. When the sharp edge is properly positioned, a physician presses a control button that actuates a relative movement between the inserted sharp edge and one or more cutting knives. The relative movement of the cutting knives punches a hole in the blood vessel.

In cutting holes in blood vessels, it is very important to perform the cutting accurately, when the hole former is correctly positioned. If the hole former is inserted too deeply, for example, it may cut a hole in a far wall of the blood vessel. In addition, if the inserted sharp edge is not sufficiently inserted, the cutting may not be carried out properly.

PCT publication WO 00/74579, the disclosure of which is incorporated herein by reference, describes a hole former in which an outer tube is advanced and optionally rotated to cut into a blood vessel from the outside, while the cut part of the blood vessel is prevented from motion or collapsing into the blood vessel by a barb coupled to the hole former.

US patent 5,129,913, the disclosure of which is incorporated herein by reference, describes a retracting shearing-cut punch, in which a non-rotating and blunt cutting head is inserted into a slit in a blood vessel and retracted while a base tube having a cutting lip is rotated. This effects a shearing cutting of a portion of the blood vessel as the cutting head is retracted towards and into the base tube.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to a hole former for hollow organs and in particular blood vessels, which automatically initiates cutting when a portion of the hole former (e.g., a sharp penetration edge) is inserted into the organ wall to a predetermined depth. In an exemplary embodiment of the invention, the sharp penetration edge forms its own opening in the blood vessel. Automatic initiation of the cutting of the blood vessel prevents errors due to manual initiation of cutting too early or too late. Alternatively or additionally, automatic initiation of cutting assists in synchronizing different parts of the cutting process, for example vessel retraction and cutter rotation.

In some embodiments of the invention, the trigger is actuated manually by contact of the trigger with a body portion, such as a wall of the blood vessel and/or body fluids. Alternatively or additionally, the trigger includes an electrical circuit which is closed when the trigger is pressed or contacted by the vessel wall, causing the initiation of the cutting of the organ wall. In some embodiments of the invention, the automatic cutting is actuated only when two separate triggers are actuated, for example, blood is detected by a first trigger and pressure of a blood vessel wall is detected by a second trigger.

Alternatively or additionally to actually performing the cutting, the actuation of the trigger causes a portion of the tube to retract and grasp the blood vessel. The cutting is then optionally performed manually. Further alternatively, the trigger is actuated by grasping the wall of the blood vessel, and the cutter cuts the blood vessel responsive to the trigger actuation. In some embodiments of the invention, the trigger is not actuated until the cutting is begun by a human operator.

In an exemplary embodiment of the invention, a trigger is positioned along-side the sharp penetration edge at a required distance from the tip of the penetration edge. When the trigger is actuated (e.g., by contact), a release mechanism causes a power source to automatically initiate the cutting. Optionally, the trigger is actuated by pressure of the outer surface of the organ wall on the trigger, due to movement of the penetration edge perpendicular to the organ wall. Alternatively, the trigger is actuated by pressure of the thickness of the blood vessel wall through which the penetration edge passed. Further alternatively, the trigger is actuated by body fluids (e.g., blood) which reach the trigger due to the entrance of the penetration edge into the blood vessel.

In an exemplary embodiment of the invention, the trigger and the release mechanism are included in a single staff (or a plurality of staffs that are fixed together). The distal end of

the trigger optionally serves as a trigger, while a proximal end of the staff includes a niche which, when moved, releases a stopper that prevents the automatic cutting initiation. The staff optionally runs parallel to a shaft carrying the penetration edge. Alternatively, the staff runs at least partially within the shaft carrying the penetration edge.

In some embodiments of the invention, when the trigger is actuated, the penetration edge is retracted, pulling back the blood vessel wall toward peripheral cutting edges of the hole former. The retraction thus at least partially cuts the blood vessel wall. The remaining cutting is optionally performed, if necessary, by rotating the hole former, so that the cutting edges cut. The retraction is optionally damped so that the retraction movement is at a desired speed and/or at a desired force level, for example a level which will not tear the penetration edge out of the wall. Alternatively, the cutting is performed by an (optionally automatic) advancement movement of the peripheral cutting edges. Further alternatively or additionally, the penetration edge and/or peripheral cutting edges rotate, automatically or manually, during advancement or retraction in order to allow easier penetration to the blood vessel wall.

In an exemplary embodiment of the invention, the retraction retracts the penetration edge and/or a plug of cut-out wall tissue into the cutting edge where it will not fall off into the blood stream.

In some embodiments of the invention, a safety latch prevents inadvertent triggering of the cutting.

There is thus provided in accordance with an exemplary embodiment of the invention, a hole former for forming an opening in a blood vessel, comprising a penetration tip adapted to be inserted through a wall of a blood vessel, a trigger which is actuated when the penetration tip is inserted up to a predetermined distance into the blood vessel; and a power source adapted to initiate a cutting process of a blood vessel, responsive to actuation of the trigger. Optionally, the power source comprises an elastic unit. Optionally, the elastic unit comprises a spring. Alternatively or additionally, the power source comprises a motor.

In an exemplary embodiment of the invention, the power source is adapted to actuate a retraction movement which initiates the cutting process. Optionally, the former comprises a damper adapted to slow the retraction movement. Optionally, the damper comprises a piston. Alternatively or additionally, the damper comprises a sponge.

In an exemplary embodiment of the invention, the power source is adapted to actuate an advancement movement which initiates the cutting process. Alternatively or additionally, the power source is adapted to actuate a rotation movement.

In an exemplary embodiment of the invention, the former comprises a controller adapted to adjust the predetermined distance. In an exemplary embodiment of the invention, the actuation of the trigger closes an electrical circuit. In an exemplary embodiment of the invention, the actuation of the trigger opens a movement path for an elastic element.

In an exemplary embodiment of the invention, the actuation of the trigger removes a stopper preventing the operation of the power source. Optionally, the stopper is located in a niche of a body portion of the hole former before the trigger is actuated and is moved to a niche of an element fixedly connected to the penetration tip upon actuation of the trigger.

In an exemplary embodiment of the invention, the stopper comprises an elastic ring. Alternatively or additionally, the stopper comprises a ball.

In an exemplary embodiment of the invention, the hole former comprises a punch which removes a section of wall tissue.

In an exemplary embodiment of the invention, the hole former comprises a cutter which forms a cut in a wall of the blood vessel.

In an exemplary embodiment of the invention, in initiating the cutting action, the power source grasps a blood vessel wall portion to be cut. Alternatively or additionally, in initiating the cutting action, the power source begins the cutting of the wall. Alternatively or additionally, in initiating the cutting action, the power source completes the cutting of the wall.

Optionally, the trigger comprises a liquid detector. Optionally, the trigger is actuated by pressure parallel to the direction of insertion of the penetration tip. Optionally, the trigger is actuated by pressure perpendicular to the direction of insertion of the penetration tip. Optionally, the trigger comprises a plurality of independent detectors.

Optionally, the cutting is initiated responsive to detection by at least one of the independent detectors.

Optionally, the cutting is initiated responsive to detection by all the independent detectors.

BRIEF DESCRIPTION OF THE FIGURES

Non-limiting embodiments of the invention will be described with reference to the following description of exemplary embodiments, in conjunction with the figures. The figures are generally not shown to scale and any measurements are only meant to be exemplary and not necessarily limiting. In the figures, identical structures, elements or parts which appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, in which:

Fig. 1A is an enlarged sectional view of a distal portion of a hole former, in accordance with an exemplary embodiment of the invention;

Fig. 1B is an enlarged sectional view of a proximal portion of the hole former of Fig. 1A, in accordance with an exemplary embodiment of the invention;

Fig. 2A is an enlarged sectional view of a proximal portion of hole former, in a proximal (released) state, in accordance with an exemplary embodiment of the invention;

Fig. 2B is an enlarged sectional view of a middle portion of hole former, in a locked state showing the operation of a safety latch in accordance with an exemplary embodiment of the invention;

Fig. 3 is a schematic illustration of a distal end of a hole former, in accordance with another exemplary embodiment of the invention;

Fig. 4 is a schematic illustration of a distal end of a hole former, in accordance with another exemplary embodiment of the invention; and

Figs. 5A and 5B show a cutter with a trigger, in accordance with an exemplary embodiment of the invention.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Fig. 1A is an enlarged sectional view of a distal portion of a hole former 100, in accordance with an exemplary embodiment of the invention. Hole former 100 includes a penetration tip 102 for insertion through a wall of a blood vessel. Optionally, penetration tip 102 includes on its proximal end, one or more barbs 114 (typically 2-4) that pop out and grasp the wall. Optionally, barbs 114 are flexible enough so that during insertion they are bent inwards (towards the axis) by the vessel wall and do not tear it. Alternatively or additionally, any other types of barbs or tissue engagement means known in the art may be used. As described below, when penetration tip 102 is sufficiently inserted, the penetration tip is retracted toward one or more peripheral knives 118 (cutters), so as to cut the vessel wall. Alternatively or additionally, as it is retracted, barbs 114 perform a knife cutting action. Penetration tip 102 is optionally mounted on a shaft 110 that runs along hole former 100 to its proximal end.

In some embodiments of the invention, a trigger 120 surrounding shaft 110, runs along side shaft 110 up to a predetermined distance behind penetration tip 102. Unlike penetration tip 102, however, when trigger 120 contacts a blood vessel wall it is pushed back or otherwise activated so as to automatically actuate a retraction of penetration tip 102, as is now described. It should be noted that this retraction is relative and in some embodiments of the invention, is

provided by a cutting edge advancing. Optionally, trigger 120 is also retracted upon the automatic activation of the cutting, for example, by trigger 120 being engaged by shaft 110 as it retracts.

Fig. 1B is an enlarged sectional view of a proximal portion of hole former 100, in accordance with an exemplary embodiment of the invention. It is noted that Fig. 1B is at a different scale than Fig. 1A. In some embodiments of the invention, a loaded spring 132 is prevented from retracting penetration tip 102, by a stopper 138. When trigger 120 is pushed back it optionally causes stopper 138 to move, thus causing spring 132 to retract penetration tip 102.

In an insertion state of hole former 100, shown in Fig. 1B, shaft 110 is supported by a shaft-base 148 (which moves together with shaft 110), which is held by a handle 144 running parallel to a proximal portion 128 of trigger 120. Handle 144 optionally comprises a hole 140 which hosts stopper 138. In the insertion state of hole former 100, stopper 138 is co-hosted by a niche 150 formed in the body of hole former 100, such that shaft-base 148, and hence shaft 110 cannot move proximally to a substantial extent.

In some embodiments of the invention, a niche 136 is formed in proximal trigger portion 128. When trigger 120 is pushed back due to an interaction with a blood vessel, stopper 138 optionally moves out of niche 150 into niche 136, allowing shaft-base 148 and shaft 110 to move backwards. In some embodiments of the invention, spring 132, surrounding shaft-base 148, is held in a loaded state by a disk 142 fixed to the proximal end of shaft-base 148. When stopper 138 exits niche 150, spring 132 is released, pushing shaft-base 148 and shaft 110 proximally. A handle 154 optionally restricts the proximal movement of shaft-base 148, so that penetration tip 102 retracts a predetermined desired distance. It should be noted that other trigger and/or release mechanisms may be used as well.

The released state of hole former 100 is shown in Fig. 2, which is an enlarged sectional view of a proximal portion of hole former 100, in a proximal (released) state, in accordance with an exemplary embodiment of the invention. In an exemplary embodiment of the invention, cutter 118 is rotationally decoupled from penetration tip 102, to prevent rotation of tip 102 and possible tearing of the blood vessel wall. Optionally cutter 118 is rotationally mounted relative to a body 130 of the cutter. Alternatively or additionally, tip 102 includes a rotational joint relative to shaft 110.

In some embodiments of the invention, the distance between the distal end of trigger 120 and penetration tip 102 is adjustable, so that it can be changed according to the specific

blood vessel treated, for example according to the wall thickness of the blood vessel and/or the diameter of the blood vessel. In an exemplary embodiment of the invention, a distal portion of trigger 120 is screwed onto proximal portion 128. By changing the amount to which the distal portion is screwed into proximal portion 128, the distance between the distal end of trigger 120 and the penetration tip 102, is adjusted.

Optionally, trigger 120 has a narrow extent near penetration tip 102 (e.g., it does not add much to the diameter of penetration tip 102), so that it is actuated due to contact with a blood vessel wall portion near the tip, which is generally level with the portion in which tip 102 is inserted. Alternatively or additionally, the distance between trigger 120 and penetration 120 is set according to the expected caving in of the blood vessel wall around tip 102.

In some embodiments of the invention, the force required to actuate trigger 120 is set above a force level which may be encountered by an inadvertent encounter of the trigger on tissue adjacent the blood vessel. Optionally, the force required in order to actuate the trigger is set to a level achievable only by pressing at least a predetermined percentage of the face area of trigger 120 against the blood vessel. In some embodiments of the invention, in order to achieve the required actuation force, at least 70-80% of the face area of trigger 120 needs to press against the blood vessel. In an exemplary embodiment of the invention, the force required for actuating the trigger is set to about 40 grams.

In some embodiments of the invention, the actuation force level is set during production according to the intended use of the hole former 100. For example, some hole formers are optionally set for a first pressure level suitable for blood vessels full of blood, while other hole formers are set for use on blood vessels with very low internal blood pressure.

Trigger 120 optionally entirely surrounds shaft 110, symmetrically covering 360°. Alternatively, trigger 120 ranges over less than the entire circumference surrounding shaft 110, for example covering between 240-300°. Such a trigger 120 is useful, for example, when the access to the blood vessel is clearer on one side than on the other. Further alternatively, the front end of the trigger is split into a plurality of separate arms, which may be symmetrical or non-symmetrical. The force required to actuate trigger 120 is optionally achieved by pressing at least a predetermined number of the front end arms against the blood vessel.

Alternatively or additionally, the trigger is not actuated if the pressure on the trigger is uneven. Optionally, the trigger has some freedom, such that if the pressure is uneven the trigger will move back at an angle and stop at a wall of the hole former before reaching the location of stopper 138.

In some embodiments of the invention, the entire front end of trigger 120 extends to a same distance from tip 102. Alternatively, the front end of trigger 120 gradually changes such that the trigger is actuated when hole former 100 is at an angle with the blood vessel. Thus, the aperture formed by hole former 100 has an elliptic shape.

In some embodiments of the invention, trigger 120 has a wide width of between 10-40% of the blood vessel diameter and/or 20-40% of the hole former diameter, so as to provide robust operation. Alternatively, in order to minimize the diameter of the hole puncher, trigger 120 is relatively narrow, having a width which is between 3-10% of the blood vessel diameter and/or 5-20% of the hole former diameter. In an exemplary embodiment of the invention, trigger 120 has a width of between about 0.5-2 millimeters, optionally about 1 millimeter. Alternatively to a single trigger 120, hole former 100 may include a plurality of separate triggers. For example, trigger 120 may be split along its entire length into two separate triggers. Each of the triggers may be connected to a separate stopper which prevents the actuation of the cutting. Only when both of the triggers actuated is the cutting performed. Alternatively, both triggers are connected to a single stopper and it is sufficient that one of the triggers is actuated in order to initiate the cutting.

The extent to which shaft 110 is retracted by spring 132 is optionally also adjustable, for example by setting the position of handle 154. Alternatively or additionally, a spacer having an adjustable distance from handle 154 is used to adjust the retraction distance, for example by inserting a spacer having a thickness between disk 142 and handle 154.

In some embodiments of the invention, the retracting of penetration tip 102 is damped, in order to achieve a desired retraction speed and/or impulse force. Optionally, the damping is performed by a sponge. Alternatively or additionally, the damping is performed by an hydraulic piston (155, Fig. 2). The damping is optionally used in embodiments in which barbs 114 need to grasp the blood vessel wall, without tearing through it. In an exemplary embodiment of the invention, the pull back force after about 2-4 mm of retraction is about 40-60 grams. The reduced speed optionally also gives an operator time to rotate the tool and achieve cutting (in those embodiments where it is needed).

In an exemplary embodiment of the invention, hole former 100 does not include a safety latch, as its operation is timed automatically. Use of hole former 100 without releasing the safety latch may cause complications, for example, in some embodiments a tissue plug may be cut off, not engaged by the barbs and then fall into the blood flow. Therefore, in order to avoid use without releasing the safety latch, a safety latch is not used.

Alternatively, for example as shown in Fig. 2B, a safety latch locks spring 132 in place, such that the spring is not released prematurely, due to inadvertent pressing of trigger 120.

In an exemplary embodiment of the invention, a safety lock 204 includes a button 206 that passes through an aperture 205 in body 130 and which, when pressed, pushes lock 204 into a recess 208. In a locked state, a projection 210 of lock 204 engages a depression 212 in trigger shaft 128, thus preventing its retraction. Pushing lock 204 into recess 208, disengages projection 210 and allows trigger shaft 128 to retract. A physician optionally releases the safety catch before hole former 100 is applied to the patient. Alternatively, the physician releases the safety catch after hole former 100 is applied to the blood vessel. It should be appreciated that other locking mechanism may be used instead.

Further alternatively or additionally, a packaging safety latch is used, which clearly prevents the use of hole former 100, for example by covering penetration tip 102 (shown in Fig. 3 as a dotted line 320).

In some embodiments of the invention, stopper 138 comprises an elastic ring. Alternatively, stopper 138 comprises a ball. The force of spring 132 as applied by handle 144 optionally impinges on the ball, such that it moves into niche 136 when the niche is parallel to niche 150.

Alternatively to using a spring 132 to actuate the retraction, in some embodiments of the invention, any other elastic unit is used. Further alternatively, the retraction is performed by a motor. Optionally, in accordance with this alternative, the movement of trigger 120 closes an electrical circuit which causes the motor to operate. A trigger which closes an electrical circuit may also be used with a spring or other elastic unit. For example, the closing of the electrical circuit may actuate a magnetic latch that removes the stopper. In some embodiments of the invention, hole former 100 includes a plurality of triggers. Optionally, all the triggers must be actuated in order to initiate the cutting, so as to prevent premature cutting. Alternatively, if one of the triggers is actuated the cutting is initiated. Thus, cases in which the cutting is not initiated due to a malfunction of one of the triggers, after a hole was perforated in the blood vessel by tip 102, are avoided. Further alternatively or additionally, any other cutting initiation function based on the trigger actuations may be used. For example, the triggers may be required to be actuated within a predetermined time from each other and/or in a specific order. The initiation logic is implemented, in some embodiments of the invention, mechanically, by a set of stoppers arranged in a manner similar to used in combination locks. Alternatively, the initiating logic may be implemented by an embedded micro-processor.

Both a spring and electric motor may be used to affect rotation of cutters 118 by the retraction of shaft 110. In one example, shaft 110 includes a thread which engages an inner thread on cutters 118. Shaft 110 optionally includes a projection (also not shown) which engages an axial notch in body 130, to prevent rotation of shaft 110.

Also shown in Fig. 2B is an optional locking mechanism for locking the punch mechanism to an external delivery tube. For example, a lock 202 may lock body 130 of the punch to an external tube (not shown) by its projection 203 locking to a matching depression or window in that body. For release, a lever 204 pulls back lock 202 so that projection 203 is retracted and the locking is released.

Fig. 3 is a schematic illustration of a distal end of a hole former 300, in accordance with another exemplary embodiment of the invention. Hole former 300 is similar to hole former 100, but has a trigger 302 with an adjustable distance from penetration tip 102. Trigger 302 is screwed onto a shaft 310 which operates similarly trigger 120 (Fig. 1B). Trigger 302 is optionally threaded with threads 304 that fit into threads 306 on shaft 310. In some embodiments of the invention, trigger 302 has a plurality of front end arms and the extent of each arm may be adjusted separately. Thus, hole former 300 may be adjusted according to the desired angle of the hole former with the blood vessel, when the hole is to be made.

Fig. 4 is a schematic illustration of a distal end of a hole former 400, in accordance with another exemplary embodiment of the invention. A shaft 410 running within shaft 110 which carries penetration tip 102, connects a trigger 402 to a proximal release mechanism (not shown). Trigger 402 projects from shaft 140, for example, by being mounted on (or formed of) a bend section 406 of shaft 410. Optionally, rotation of trigger 402 or selection of different trigger diameters allows a physician to adjust the distance of the far edge of trigger 402 from penetration tip 102. An opening 412 in shaft 110 allows the connection of trigger 402 to shaft 410. Opening 412 is optionally sufficiently large to allow sufficient axial movement of shaft 410 required to release the spring or other power source used to actuate the retraction.

In an alternative embodiment of the invention, blood enters opening 412 and applies pressure (or electrical contact) to a suitable trigger that is inside shaft 110. Alternatively or additionally, the wall of the blood vessel itself applies pressure to a pressure sensor provided in shaft 110. For example, an aperture 412 may be covered with a flexible membrane and serve as such a window. An overtube is optionally positioned over the aperture to adjust the trigger position.

Although the above description relates to cutting blood vessel walls, the hole formers of the present invention may be used with walls of other organs, as well as with walls of artificial blood vessels (grafts).

Although the above description relates to a hole cutter that initiates the cutting by retraction, the methods of the present invention may be used with a hole cutter that cuts by a forward movement of the peripheral knife or knives. The release of a loaded spring, in such embodiments, may actuate the forward movement. Alternatively or additionally, as noted above for example, the release of the loaded spring may provide rotation of cutters 118.

In some anastomotic connection systems a single overtube is used as a guide for the punch (provided as a first tool) and for providing a graft with a connector (as a second tool). In one implementation of such a system, after the hole forming is completed, an overtube is advanced over the cutting blades so it is located in the formed hole between the cutting blades and the wall of the blood vessel. In an exemplary embodiment of the invention, however, cutters 118 themselves serve the function of the overtube, e.g., for later delivery of an anastomotic connector, instead of providing a separate over-tube over the punch device and into the aperture formed in the blood vessel. Optionally, a leaf-valve or other type of valve is provided between cutters 118 and shaft 110, to seal the blood in. The feature of using cutters as an overtube may be provided in other, non-automatic, implementations of the punch.

It will be appreciated that the above described hole former may be varied in many ways, including, changing the types of stoppers and springs used. It should also be appreciated that the above described methods and apparatus are to be interpreted as including apparatus for carrying out the methods and methods of using the apparatus.

The automatic cutting method of the present invention is not limited for use with any specific hole cutter. Particularly, the automatic cutting method may be used with shear and anvil cutters, inner and outer cutters, cutters requiring rotation (e.g., partial turn, entire turn, right, left). For example, the automatic initiation mechanism may be used for the punches and/or for performance of anastomotic connection and/or delivery of anastomotic connectors, described in one or more of PCT publications WO 99/62415, WO 00/56226, WO 00/56228, WO 01/41623, WO 01/41624, WO 01/70091, WO 01/70118, WO 01/70119, WO 01/70090, WO 02/47561, WO 02/30172, WO 02/47532, WO 02/074188, WO 03/026475 and PCT applications number PCT/IL03/00769, PCT/IL03/00770, PCT/IL03/00771 PCT/IL03/00773 PCT/IL03/00774 all filed on September 25, 2003 and PCT/IL03/00959 filed on November 13,

2003 and in US provisional applications 60/426,013, 60/505,946 and 60/518,677 the disclosures of which are incorporated herein by reference.

In particular, the automatic tip retraction and tip covering mechanisms described in WO 02/074188 and WO 01/70091, are optionally used to trigger retraction. Alternatively, the trigger mechanism described herein, may be used for tip retraction and/or tip covering.

Figs. 5A and 5B show a cutter 500 with a trigger 510, in accordance with an exemplary embodiment of the invention. As in some of the above described embodiments, when cutter 500 is inserted into the blood vessel, trigger 510 is triggered by the completion of the insertion act and the cutting is then initiated automatically. Alternatively, some additional motion may be required in order to actuate trigger 510, for example advancing cutter 500.

In Fig. 5A, a scythe-type cutter is shown, having an arcuate scythe body 504 which includes a sharp tip 508 used for penetrating a wall of vessel 502. Then, scythe body 504 is rotated around its axis (e.g., a point 507) so that the body follows point 508 into the blood vessel. When such insertion is completed, trigger 510 which is located at a point diametrically opposite point 508 and optionally slightly pulled back (e.g., to allow for the blood vessel wall thickness), as a matter of course contacts vessel 502 and causes scythe body 504 to retract. An inner blade 506 of body 504 performs the cutting and penetration point 508 optionally fixes the blade relative to the blood vessel so cutter 500 does not move during cutting.

Fig. 5B shows scythe body 504 retracted into a body section 512 of cutter 500 (shown as if part of body 512 were invisible) and vessel 502 cut.

Although in the above description the trigger initiates cutting of the blood vessel, in some embodiments of the invention, other acts may be initiated automatically by the trigger in addition to, or instead of, the cutting. For example, a trigger rod may be used to initiate the retraction and/or tearing of anastomosis connector legs, for example in a device as described in the above PCT applications, or in US provisional application 60/505,946, a trigger rod to the side of the device can be used to advance the delivery system, retract connector legs and/or tear connector legs.

Optionally a triggering system is used to initiate a complete process of connector device deployment, including one or more of grasping, incision, connector insertion, connector deployment and graft vessel release. Such a system may be powered, for example manually (e.g., with next step being allowed but requiring a human power input and/or confirmation), hydraulically, for example as described in US provisional application 60/518,677, or using a spring.

The present invention has been described using non-limiting detailed descriptions of embodiments thereof that are provided by way of example and are not intended to limit the scope of the invention. It should be understood that features and/or steps described with respect to one embodiment may be used with other embodiments and that not all embodiments of the invention have all of the features and/or steps shown in a particular figure or described with respect to one of the embodiments. Variations of embodiments described will occur to persons of the art.

It is noted that some of the above described embodiments may describe the best mode contemplated by the inventors and therefore may include structure, acts or details of structures and acts that may not be essential to the invention and which are described as examples. Structure and acts described herein are replaceable by equivalents which perform the same function, even if the structure or acts are different, as known in the art. Therefore, the scope of the invention is limited only by the elements and limitations as used in the claims. When used in the following claims, the terms "comprise", "include", "have" and their conjugates mean "including but not limited to".

CLAIMS

1. A hole former for forming an opening in a blood vessel, comprising:

a penetration tip adapted to be inserted through a wall of a blood vessel;

a trigger which is actuated when the penetration tip is inserted up to a predetermined distance into the blood vessel; and

a power source adapted to initiate a cutting process of a blood vessel, responsive to actuation of the trigger.

2. A hole former according to claim 1, wherein the power source comprises an elastic unit.

3. A hole former according to claim 2, wherein the elastic unit comprises a spring.

4. A hole former according to claim 1, wherein the power source comprises a motor.

5. A hole former according to claim 1, wherein the power source is adapted to actuate a retraction movement which initiates the cutting process.

6. A hole former according to claim 5, comprising a damper adapted to slow the retraction movement.

7. A hole former according to claim 6, wherein the damper comprises a piston.

8. A hole former according to claim 6, wherein the damper comprises a sponge.

9. A hole former according to claim 1, wherein the power source is adapted to actuate an advancement movement which initiates the cutting process.

10. A hole former according to claim 1, wherein the power source is adapted to actuate a rotation movement.

11. A hole former according to claim 1, comprising a controller adapted to adjust the predetermined distance.

12. A hole former according to claim 1, wherein the actuation of the trigger closes an electrical circuit.

13. A hole former according to claim 1, wherein the actuation of the trigger opens a movement path for an elastic element.

14. A hole former according to claim 1, wherein the actuation of the trigger removes a stopper preventing the operation of the power source.

15. A hole former according to claim 14, wherein the stopper is located in a niche of a body portion of the hole former before the trigger is actuated and is moved to a niche of an element fixedly connected to the penetration tip upon actuation of the trigger.

16. A hole former according to claim 14, wherein the stopper comprises an elastic ring.

17. A hole former according to claim 14, wherein the stopper comprises a ball.

18. A hole former according to claim 1, wherein the hole former comprises a punch which removes a section of wall tissue.

19. A hole former according to claim 1, wherein the hole former comprises a cutter which forms a cut in a wall of the blood vessel.

20. A hole former according to claim 1, wherein in initiating the cutting action, the power source grasps a blood vessel wall portion to be cut.

21. A hole former according to claim 1, wherein in initiating the cutting action, the power source begins the cutting of the wall.

22. A hole former according to claim 1, wherein in initiating the cutting action, the power source completes the cutting of the wall.

23. A hole former according to claim 1, wherein the trigger comprises a liquid detector.

24. A hole former according to claim 1, wherein the trigger is actuated by pressure parallel to the direction of insertion of the penetration tip.

25. A hole former according to claim 1, wherein the trigger is actuated by pressure perpendicular to the direction of insertion of the penetration tip.

26. A hole former according to claim 1, wherein the trigger comprises a plurality of independent detectors.

27. A hole former according to claim 26, wherein the cutting is initiated responsive to detection by at least one of the independent detectors.

28. A hole former according to claim 26, wherein the cutting is initiated responsive to detection by all the independent detectors.

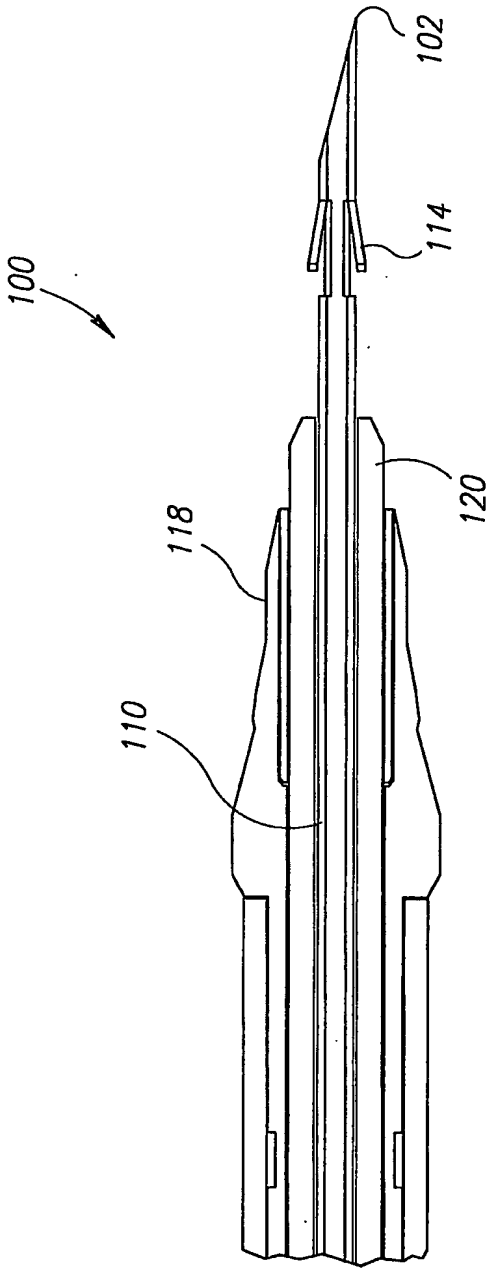

FIG.1A

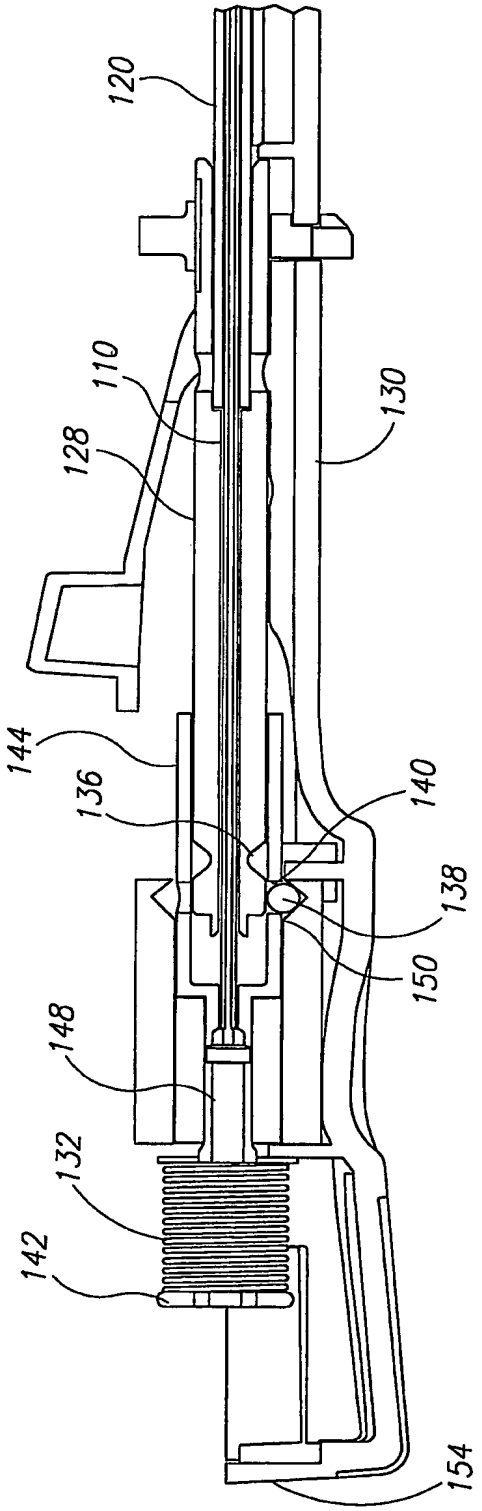

FIG.1B

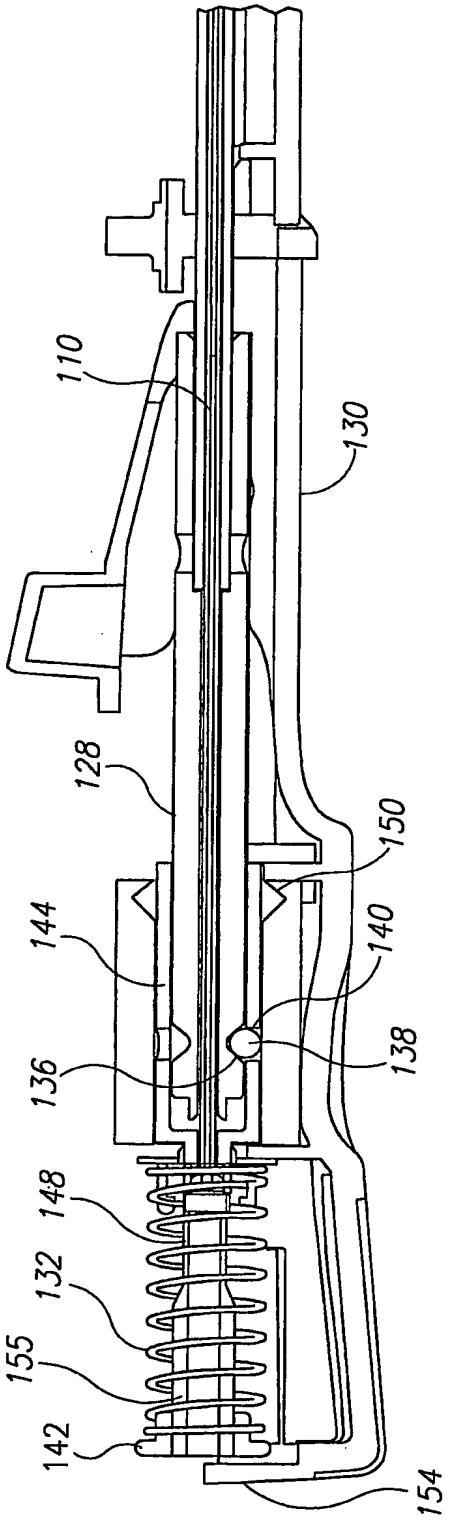

FIG.2A

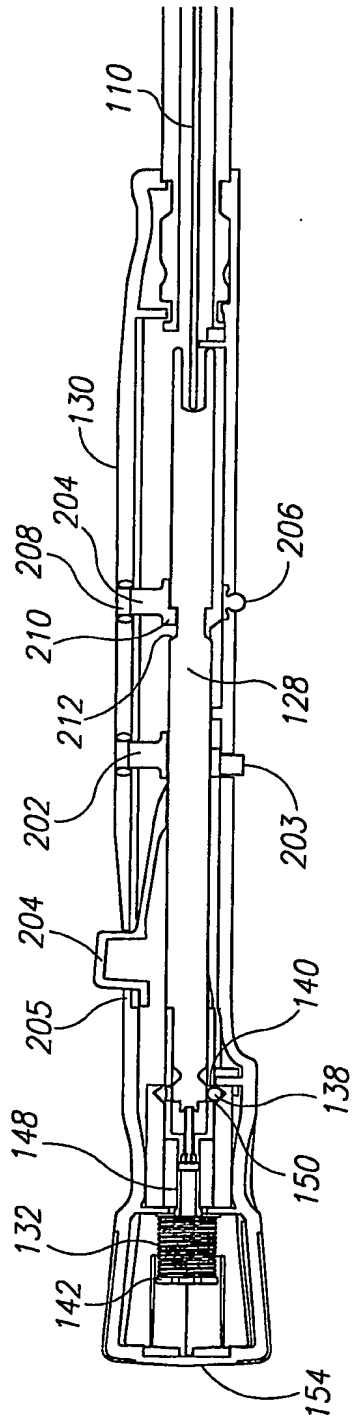
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FIG.2B

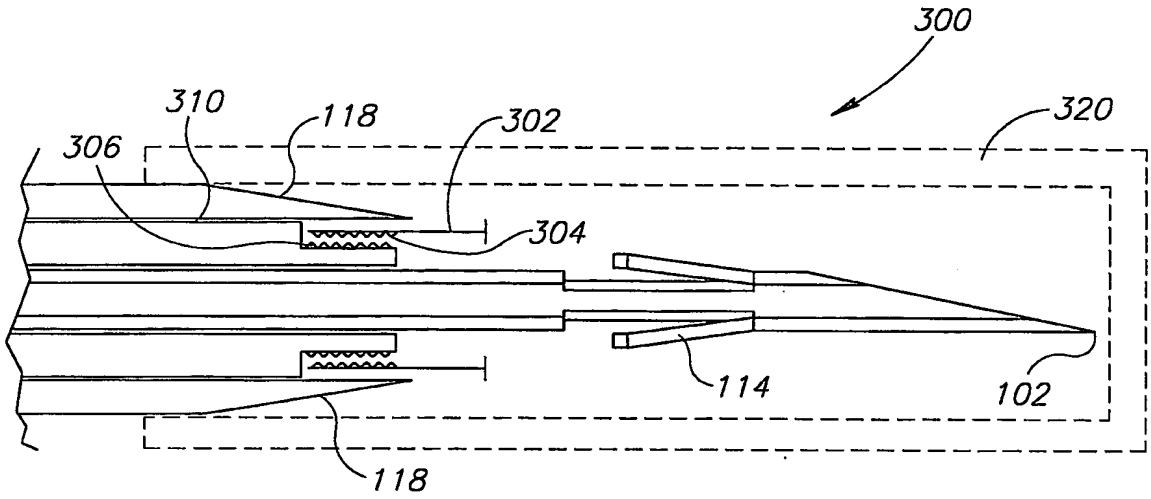
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FIG.3

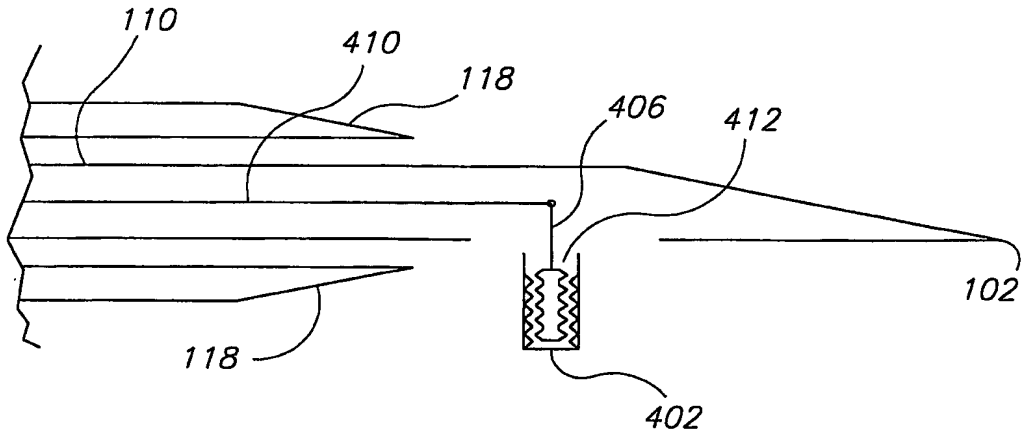
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FIG.4

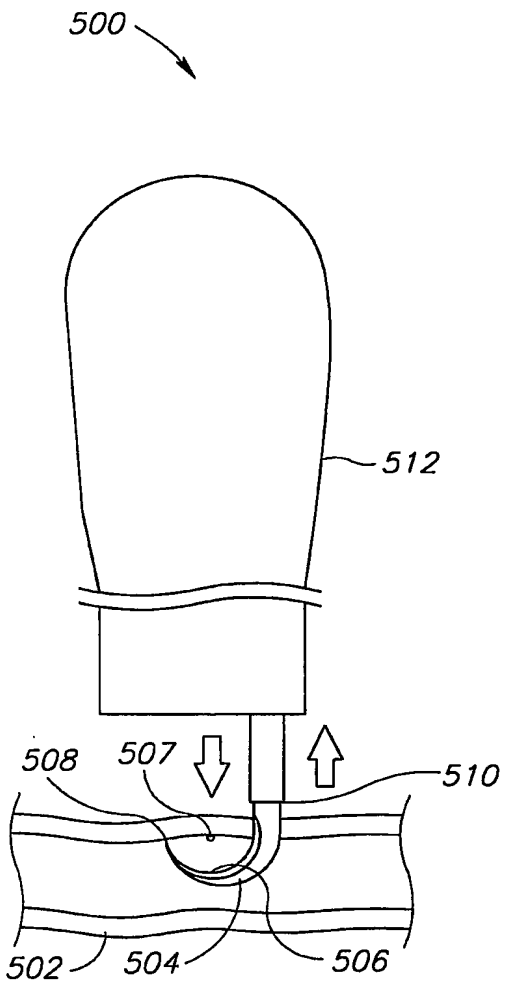

FIG.5A

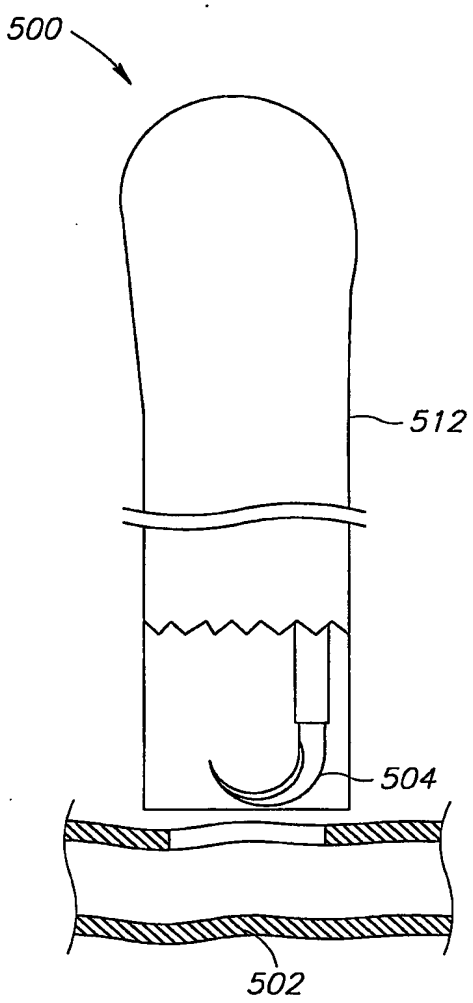

FIG.5B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL04/00311

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) : A61B 17/34
US CL : 606/159
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 606/159, 170, 182, 184, 186

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2002/0169470 A1 (KUHR et al.) 14 November 2002 (14.11.2002), See paragraph [0031, 0035]	1, 11, 13, 14, 22
X	US 5,685,838 A (PETERS et al.) 11 November 1997 (11.11.1997), See column 5, lines 54-59; column 4, lines 4-7; Fig. 2	1, 4-8, 21
X	US 6,080,176 A (YOUNG) 27 June 2000 (27.06.2001), See column 3, lines 16-22; Fig. 2	1-3, 5, 9, 18, 19, 24

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
06 August 2004 (06.08.2004)

Date of mailing of the international search report
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Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
Facsimile No. (703) 305-3230

Authorized officer
Bradford C Pantuck

Telephone No. (703) 308-0858

Sheila H. Veney
Paralegal Specialist
Tech. Center 3700

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